

October 25, 2002

Ms. Vicki Morris, MS, CHP  
Radiation Safety Officer  
University of Cincinnati  
P.O. Box 670591  
231 Albert Sabin Way  
Cincinnati, OH 45267-0591

Dear Ms. Morris:

Thank you for your September 4, 2002 e-mail inquiry regarding the compatibility designation of paragraphs (b) and (c) of 10 CFR 71.10, "Exemption for low-level materials." In response to your concerns, we have enclosed a clarification of the applicable current regulations. Specifically, you raised concerns regarding the change in compatibility designation of 10 CFR 71.10 (b) and (c) from Category B, which requires Agreement State adoption, to a Category "NRC," which cannot be adopted by an Agreement State. In addition, you requested that the NRC re-evaluate the current compatibility designation of 10 CFR 71.10 (b) and (c), and consider changing their designation to either compatibility Category B or C.

The enclosed document provides a detailed analysis and summary explanation of the compatibility designation, "NRC," for §71.10 (b) and (c) exemptions, including whether or not the requirements are applicable to a specific type and quantity of radioactive material, and specific type of package. For example, if you are a low risk shipper, you are exempt from those requirements in 10 CFR Part 71 which apply to Type B packages. This exemption is achieved in Agreement States by requiring States to adopt only those portions of Part 71 that apply to low risk shipments. Those portions of Part 71 which apply to the approval of high risk packages (e.g., Type B packages) cannot be adopted by States. The authority to approve Type B packages is reserved to the NRC and cannot be relinquished to States. Finally, as an Agreement State low risk shipper, you would continue to ship under U.S. Department of Transportation (DOT) requirements or State equivalents of DOT requirements for Type A packages.

If you have any further questions, please contact Ms. Cardelia Maupin of my staff at 301-415-2312 or e-mail: [chm1@nrc.gov](mailto:chm1@nrc.gov).

Sincerely,

**/RA/**

Paul H. Lohaus, Director  
Office of State and Tribal Programs

Enclosure:  
As stated

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Policy &amp; Guidance File

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## **RESPONSE TO CONCERNS RAISED REGARDING COMPATIBILITY DESIGNATION OF 71.10 (b) and (c)**

Concern 1: You indicated that deleting the equivalent to 10 CFR 71.10 (b) and (c) from the rule significantly changed how licensees must handle "low risk shipments" of radioactive materials.

Response: The revision of compatibility designation will not change the shipping requirements for Type A packages and other "low risk shipments" of radioactive materials described in 10 CFR 71.10 (b) and (c). These types of shipments will continue to be regulated by applicable DOT regulations in 49 CFR, and State transportation regulations equivalent to DOT regulations.

Background: Section 71.10 (b) provides, "A licensee is exempt from all requirements of this part, other than §71.5 and §71.88, with respect to shipment or carriage of the following packages, provided the packages contain no fissile material, or the fissile material exemption standards in §71.53 are satisfied:..." Section 71.10(c) provides, "A licensee is exempt from all requirements of this part other than §71.5 and §71.88, with respect to shipment or carriage of low-specific-activity (LSA) material in LSA-I, or surface contaminated objects (SCOs) in group SCO-I."

The Part 71 Statement of Considerations, which provides background on the rationale for the development of the rule, indicates,

"The provisions of §71.10, 'Exemption for low-level materials,' provide broad exemptions from 10 CFR Part 71 rules that relinquish to DOT the control of types of shipments that are of low risk both from radiation and criticality standpoints. To ensure that only low criticality risk shipments are included in §71.10 (b), NRC restricts the exemption to Type A and LSA packages that either contain no fissile material or satisfy the fissile material exemptions in §71.53. It should be noted that the exemption does not relieve licensees from the DOT transportation requirements, by reason of NRC authority, nor does the exemption relieve licensees from the restrictions on air transportation of plutonium imposed by Congress."

With regard to the adoption of these exemptions by States, DOT has advised that State radiation control programs should not include 10 CFR 71.10 (b) and (c) exemptions in their program. DOT indicated that inclusion of these exemptions would limit States' ability to implement all of 49 CFR and to not include these exemptions would preserve a radiation control program's ability to inspect Type A quantity transport. (See the attached 1999 Rationale for Revisions, Part T Transportation of Radioactive Material, page 2, paragraph four, and pages 5-6, Sec. T.4-Exemptions and the 1999 copy of Part T, Attachment 1.)

During the NRC staff reevaluation of the compatibility designation for 10 CFR 71.10 (b) and (c), we also determined that State radiation control programs should not adopt these exemptions. The adoption of these exemptions by State radiation control programs could cause a potential conflict in the regulation of the transportation of low risk materials. In addition, a conflict could occur when the State's DOT regulations sets out requirements for Type A packages, and the 10 CFR 71.10 (b) and (c) exemptions, if adopted, would exempt shippers from complying with these requirements. In essence, the exemptions could potentially nullify the State's Type A shipping requirements in the Agreement State.

As noted in the Statement of Considerations above, the inclusion of these provisions in the NRC regulations informs shippers of low risk materials that they do not have to comply with those requirements in 10 CFR Part 71 that apply to Type B packages. These provisions also inform Type A shippers that they must comply with the DOT regulations cited in 10 CFR 71.5.

This exemption is achieved in Agreement States by requiring States to adopt only those portions of Part 71 that apply to low risk shipments. Those portions of Part 71 which apply to the approval of high risk packages (e.g., Type B packages) cannot be adopted by States. The authority to approve Type B packages is reserved to the NRC and cannot be relinquished to States because Type B packages are used to transport SNM in quantities sufficient to form a critical mass. As a result, there is no need to require Agreement States to adopt the §71.10 (b) and (c) exemptions because the sections of Part 71 which are being exempted by these provisions cannot be included in the State's regulations.

Moreover, although the §71.10 (b) and (c) provisions direct Type A shippers to comply with DOT regulations referenced in 10 CFR 71.5, the reference is incomplete. The NRC staff determined that the reference does not fully reflect all of the applicable DOT regulations, e.g., 49 CFR Parts 390-397, "Federal Highway regulations." Thus, in order to eliminate potential confusion, Agreement State's should not adopt the 10 CFR 71.10 (b) and (c) provisions.

Concern 2: You indicated that 10 CFR 71.10 (b) and (c) consists of exemptions from the majority of the regulations listed in 10 CFR 71 for "lower risk shipments" (e.g., Type A or less quantity, selected low specific activity (LSA) or surface contaminated object (SCO) shipments, less than 20 Ci of Am and Pu). You also indicated that the exemptions in 10 CFR 71.10 (b) and (c) release licensees from all parts of 10 CFR 71 except that part which requires a licensee to follow DOT regulations (i.e., 10 CFR 71.5) and that part which restricts air shipments of Pu (i.e., 10 CFR 71.88). You further indicated that by eliminating the exemptions listed in 10 CFR 71.10 (b) and (c) the effect is that all parts of 10 CFR 71 would now apply to all shipments of radioactive material, including "low risk shipments."

Response: The elimination of the exemptions in 10 CFR 71.10 (b) and (c) as a matter of compatibility for Agreement States does not subject an Agreement State low risk shipper to all of the requirements in 10 CFR Part 71. As discussed in Concern 1, low risk shippers are subject to DOT regulations applicable to Type A packages. The other requirements in Part 71 by their terms do not apply to Type A packages.

Background: See concern 1 above.

Concern 3: You indicated that requirements added by changing the compatibility designation of 10 CFR 71.10 (b) and (c) would result in having all transportation packages approved by the NRC, and having a NRC or Agreement State approved quality assurance programs, as described in 10 CFR 71 subpart H.

Response: Type A shippers are not subject to the 10 CFR Part 71 Quality Assurance program requirements in Subpart H. This program applies to Type B shippers of materials. If an Agreement State chooses, it may establish a quality assurance program for Type A packages. This would be consistent with the DOT requirements in 49 CFR 173.475, "Quality control

requirements prior to each shipment of Class 7 (radioactive) materials,” which already applies to all shipments of radioactive material.

Background: The Memorandum of Understanding for Transportation of Radioactive Materials (MOU) between the NRC and the DOT, delineates the respective responsibilities and roles of DOT and the NRC in the regulation of radioactive materials, Attachment 2. Generally, the MOU provides that the NRC adopts requirements to regulate the design specifications and performance requirements of packages for shipment of fissile materials and quantities of radioactive materials exceeding Type A limits, except for low specific activity materials, i.e., Type B packages. Thus, 10 CFR Part 71 can be viewed as the “procedures and standards for NRC approval of packaging and shipping procedures for material required to be transported in a Type B package and fissile material in Type A packages.” The MOU provides that DOT adopts requirements to regulate the approval of packages for quantities of low specific activity radioactive materials and radioactive materials not exceeding Type A limits, except for fissile Type A packages and all other transportation requirements. In addition, DOT issues the complete and comprehensive Federal regulations for the packaging and transportation of all radioactive materials as a part of its overall body of Federal regulations for the packaging and transportation of all hazardous materials. Thus, when an Agreement State adopts DOT regulations, there are very few additional 10 CFR Part 71 requirements that are needed. Please see the attached All Agreement States letter (STP-01-029) dated March 29, 2001 on the subject of adopting certain transportation regulations by reference, Attachment 3.

Concern 4: You requested the NRC reevaluate the current compatibility assigned to 10 CFR 71.10 (b) and (c) and seriously consider changing it back to compatibility B or possibly to compatibility C.

Response: In 2000, at the request of an Agreement State, we reevaluated the compatibility designation of Category B for 10 CFR 71.10 (b) and (c). Based upon the DOT determination that these exemptions in a State’s program would conflict with regulations addressing Type A packages and our reevaluation of the provisions, we determined that the designation of “NRC” is appropriate.

Background: The adoption of DOT regulations by reference in 10 CFR 71.5 and by Agreement States in their regulations augments the DOT inspection and enforcement efforts with those of the NRC and the Agreement States. The combined efforts of DOT, NRC, and the Agreement States assure that the applicable Federal regulations are observed with respect to packaging and shipping of radioactive materials on a nationwide basis. However, since Agreement States adopt DOT rules covering Type A packages and do not adopt NRC rules governing the approval of Type B packages, to insert an exemption to Type A packing and shipping requirements by adopting the provisions in 10 CFR 71.10 (b) and (c) would be confusing. Please see Attachment 1, SSR Part T, which are model State transportation regulations which demonstrate that 10 CFR 71.10 (b) and (c) are not needed in State radiation control program transportation regulations.

Attachments:  
As stated